Novel Endpoints Generated by Mobile Accelerometry for Use in Phase III Clinical Trials

>> MARCH 07, 2018 <<

Venue
Klinikum rechts der Isar Technische Universität München
Ismaninger Str. 22 - 81675 Munich
Auditorium B

Register till February 28th, 2018

Scan QR-Code or go to:

https://goo.gl/forms/CQlQvBfVV9wQN3qz1

Webinars on IMI2 - Call 13

We are pleased to inform you that an IMI Call is now open which offers significant harmonization with the topics of our forthcoming Winter Symposium.

There will be an important Webinar to discuss the call and answer potential applicants' questions.

Linking digital assessment of mobility to clinical endpoints to drive regulatory acceptance and clinical practice
Thursday 14 December, 10:30 - 12:00 (Brussels time)
Register

Source: http://www.imi.europa.eu/news-events/events/webinars-imi2-call-13

Please register for this Webinar by clicking the link above or scanning this QR-Code:

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TOPIC: Linking digital assessment of mobility to clinical endpoints to support regulatory acceptance and clinical practice

Topic identifier:	IMI2-2017-13-07		
Publication date:	30 November 2017		
Types of action:	IMI2-RIA Research and Innovation action		
DeadlineModel:	two-stage	**Deadline:**	28 February 2018 17:00:00
Opening date:	30 November 2017	**2nd stage Deadline:**	06 September 2018 17:00:00

Time Zone : (Brussels time)

Topic Description

Specific Challenge:

Loss of mobility is a growing unmet medical need, driven by chronic illness and frailty in the elderly and by injury in the young. Loss of mobility is a key morbid effect of diseases of various organ systems, including chronic obstructive pulmonary disease (COPD), heart failure, multiple sclerosis, neurodegenerative diseases, etc. New therapeutic approaches target restoration of function and mobility in patients with degenerative diseases, acute injuries, and age-related disabilities, such as muscle anabolic drugs, cartilage regeneration approaches, and other therapies targeting the musculoskeletal system.

However, current primary endpoints that measure mobility are either based on patient reported outcome or performance testing, both of which have significant shortcomings.

To ensure full acceptance and integration of digital mobility assessment into clinical trials and utilisation as primary or secondary endpoint, there is a need for rigorous validation and linkage to clinically relevant 'hard' endpoints, such as death, disability, falls, or other complications.

Scope:

The purpose of the action is to measure in three chronically ill or frail populations (e.g. heart failure, multiple sclerosis, Parkinson's disease, COPD, frailty/ sarcopenia, post-hip fracture):

- as a primary outcome, real world walking speed (RWS);
- as secondary outcomes, additional digital mobility assessment (step counts, time walking, gait characteristics, time sitting/ standing/walking, cadence, estimated energy expenditure of physical activity, etc.) to be collected and compared (or combined) with RWS to identify outcomes of maximum predictive power.

The action will demonstrate that RWS or one of the other gait parameters predicts relevant medical outcomes (falls, injurious falls, hospitalisations, loss of activities of daily living [ADLs], death), and achieve regulatory recognition of RWS as a surrogate endpoint independently of underlying disease diagnosis. To do this, regulatory submission for qualification opinion is anticipated.

Expected Impact:

By making mobility assessment feasible, and indeed an integral part of medical care, this could enable development of novel solutions (pharmacological, digital, nutritional, exercise-based) to a major public health problem – the increasing prevalence of mobility disability due to the aging of the population and chronic diseases. The digital assessment of mobility is such a method, and has the potential to revolutionise the care of frail populations and of the development of drugs to treat them.

Successful demonstration that digitally-detected low mobility predicts relevant clinical outcomes will have major impact on drug development and clinical care of the target population.

Source: http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/imi2-2017-13-07.html

CONFIRMED SPEAKERS | TOPICS

Confirmed Speakers:

Bill Byrom, ***ICON plc***
Senior Director of Product Innovation,
Vice Director of ePRO Consortium

Martin Daumer, ***SLC-Human Motion Institute***
Scientifc Director of SLCMSR e.V. - The Human Motion Institute,
Trium Analysis Online, TU Munich

Thomas M MacDonald, ***University of Dundee***
Director of MEMO Research
Professor & Consultant Physician

Jörn Rittweger, ***German Aerospace Center***
Head of the Division of Muscle and Bone Metabolism

Dieter Rosenbaum, ***Otto Bock***
Director Biomechanics Research
Clinical Research and Services

Bernd Grimm, ***Past-President EORS***
Fellow of International Orthopaedic Research

Topics:

- **Sensor technology and assessment criteria**
- **Endpoints based on mobile accelerometry**
- **Validation and steps towards regulatory acceptance**
- **Wearables & clinical trials**
- **Walking in chronic diseases & rehabilitation**
- **Walking and cognition/dual tasking**
- **Walking/running/exercise in space, Bed rest studies**
- **Myokines**
- **Walking and falling**
- **Shoes and risk of injuries**
- **Maternal/fetal motion**
- **Acceleromics**
- **Devices and gold standards**
- **Big data and open access**
- **Regulatory aspects for novel outcomes**

The organizers reserve the right for rearrangements

Interested to present a poster, give a talk or exhibit?
Please contact:

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The Human Motion Institute
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REGISTRATION

Registration fee

Industry	**400€**
Public research institution	**250€**
PhD students	**100€**
Students	**50€**
Students presenting poster	**free**
Interested patients	**free**
Press	**free**
Speakers	**free**

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Last minute registration: plus 20%
All Fees include 19% VAT
Fee includes drinks & lunch

Payment of Fees
All fees for registration should be paid in Euro (€) in advance to Sylvia Lawry Centre e.V. – The Human Motion Institute, stating the participant's name and address. Bank charges are the responsibility of the payer and should be paid in addition to the registration fees. Payment can be effected by bank transfer to:

Account holder/beneficiary:
Sylvia Lawry Centre for Multiple Sclerosis Research e.V.
Financial institution:
HypoVereinsbank Munich
Innere Wiener Str. 60 - 81667 München
SWIFT/BIC HYVEDEMMXXX
IBAN-Code DE70 7002 0270 00 36 198 214

Confirmation
Upon receipt of the correct registration fee, each participant will receive a confirmation of registration. Please bring this confirmation to the registration desk as proof of your registration.

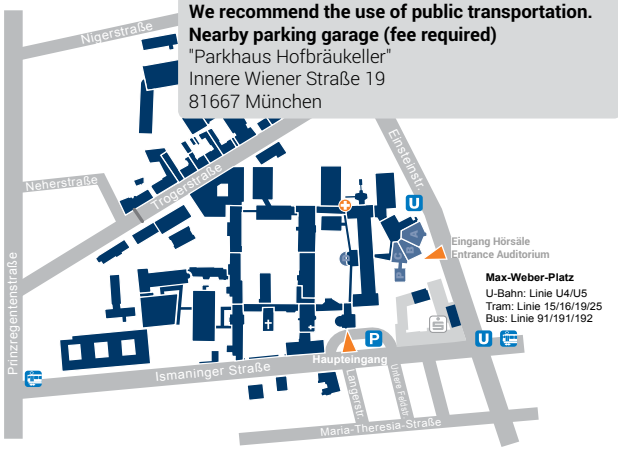
Cancellation Policy
Refund of registration fees will be as follows:
- until end of January 2018: 100% refund
- until end of February 2018: 50% refund
- No refund on cancellations after March 4th , 2018

REGISTRATION CLOSING DATE
WEDNESDAY FEBRUARY 28TH, 2018

GENERAL INFORMATION

Site Map

We recommend the use of public transportation.
Nearby parking garage (fee required)
"Parkhaus Hofbräukeller"
Innere Wiener Straße 19
81667 München



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